REMARKS

Claims 7-9 and 26-28 are pending in the application. Claims 27-28 have been cancelled and claim 7 has been amended. Reconsideration of claims 7-9 and 26 is respectfully requested.

Rejection under Section 101 and 112, first paragraph.

Claims 7-9 and 26-28 stand rejected under Section 101 and Section 112, first paragraph. These rejections are based upon Examiner's assertion that the invention lacks utility for monitoring mucosal immunity and immune dysfunction. These rejections are respectfully traversed.

First, it may be noted that claims 7-9 and 26 do not in any way relate to monitoring mucosal immunity or immune dysfunction and the only claims that related to this issue, i.e., claims 27-28, have been cancelled. It is, therefore, believed that this issue is now moot or obviated.

It is further noted that the remaining claims 7-9 and 26 relate to immunocoprocytes bearing IgC, IgA , CFc or a combination thereof. And, to be sure that these cells meet the requirement of a utility under Section 101, experimental data have been presented in Table 2 at page 21of the specification according to the methodology for how to make and use these cells described at length in the application. As shown in Table 2, the relative distribution of these cells in normal subjects has been determined. Since the colonic cells are well recognized by one of ordinary skill in the art to which this invention belongs, to be true representative of the anatomical and pathophysiological condition of the entire colon, a deviation from the normal distribution presented in Table 2 would, of course, be indicative of some abnormality, which *per se* would serve as a useful indicator for further investigation or tests and the like. This utility alone, without more, suffices the requirements of Section 101. In other words, claims 7-9 and 26 are not violative of Section 101. And, as noted above, the data presented in Table 2 have been obtained by detailed techniques and methodology described in the application, which fully meet the requirement of Section 112, first paragraph, of how to make and use these cells. Hence, it is believed that the claims are not violative of Section 112, first paragraph, either.

Rejection under Section 102

Claims 7-9 and 26-28 were rejected under 35 U.S.C. 102(b) as being anticipated by Dutta et al cited by the Examiner. This rejection is respectfully traversed.

In rejecting the claims the Examiner asserts that the immunocoprocytes are a subset of the colonocytes of Dutta et al. It is believed that this assertion is not correct because the colonocytes obtained by the applicant are totally distinct and different from those obtained by Dutta et al. In particular, it may be noted that Dutta does not disclose nor obtains colonocytes of the nature and properties as recited in the claims, i.e., **with a yield of about 8-10 million living colonocytes per gram of fecal matter**, an accomplishment not heretofore achieved. It may be important to note here that the methodology employed by *Dutta et al* is, first of all, incapable of producing the type and purity of colonocytes as required and obtained by the unique and distinctive isolation process described in the specification of the present invention. Secondly, even if *arguendo* substantially pure isolated colonocytes are obtained, further techniques and processes must be employed to obtain a distinctive group of cells identified as "IMMUNOCOPROCYTES" (described on page 13 of the present specification under the same subheading), which are unique in expressing immunoglobulins; that also not one but three distinctly different immunoglobulins. It may be important and quite notable at this point that if the methodology and techniques in accordance to the present invention for isolating colonocytes are different from those employed by Dutta et al, there is no way to predict *a priori* that the cells obtained thereby shall have **the same** characteristics, nature and/or properties. Since immunocoprocytes' nature, properties and characteristics as bearers of several immunoglobulins were heretofore not known, it is unimaginable how such unique cells could have been inherently anticipated. In short, there is no disclosure or teaching in any prior art to inherently anticipate the claimed invention. Thus, if the colonocytes obtained by Dutta et al are not the **same** as those obtained by the applicant, whatever else Dutta's colonocytes may possess is of no significance in so far as the inherency or anticipation requirement of Section 102(b)

is concerned. Indeed, Dutta did not disclose any entity bearing the immunoglobulins as discovered by the applicant. And, it is mere hindsight to speculate and assert, without any evidence whatsoever, that the immunocoprocytes of the present invention are a subset of Dutta et al's colonocytes. **This would be true if, and only if, the colonocytes of Dutta et al were the same as those of the present invention which, of course, is not true.** Needless to say that anticipation requires identical or same invention, which is not the case with the presently claimed subject matter. Hence, the rejection under Section 102(b) is inapplicable and this rejection should now be withdrawn.

Rejection under 35 U.S.C.103

Claims 7, 9 and 27-28 are rejected under 35 U.S.C.103 as being obvious over Kobayashi et al in view of Dutta et al cited by the Examiner. This rejection is respectfully traversed.

In rejecting the claims the Examiner states that Kobayashi et al specifically teach that Fc binding site might be involved in immunologic defense of the gut, although Kobayashi et al do not teach immunocoprocytes isolated from fecal matter. To compensate for this deficiency of Kobayashi et al, the Examiner relies upon Dutta et al for the proposition that Dutta et al teach isolation of colonocytes and then the Examiner asserts that the immunocoprocytes are a subset thereof.

As set forth in the remarks above pertaining to Section 102 rejection, the methodology and the colonocytes obtained by Dutta et al are distinctly different from the present invention and it cannot be *a priori* asserted that the colonocytes isolated from fecal matter by a process distinctly different from that of the cited prior art will express immunoglobulins of any kind, let alone Fc in particular.

Furthermore, it should be noted that claims 27-28 which relate to immune function have been cancelled, and claims 7 and 9 do not in any manner relate to immune function or dysfunction. Moreover, *prima facie* obviousness implies similar results be obtainable without undue experimentation. Since, (i) the process and the product (colonocytes) obtained by the methodology of the present invention are distinctly different; and (ii) it cannot be *a priori* assumed that the isolated colonocytes will bear

immunoglobulins (even if *arguendo* the colonocytes were not distinctly different), it will only be hindsight to assert that the immunocoprocytes of the present invention would have been *prima facie* obvious.

For the reasons stated above, it is believed that rejection of claims 7 and 9 (27-28 having been cancelled) under 35 U.S.C. 103 is not applicable and this rejection should be withdrawn.

In light of the above, the application is now believed to be in condition for allowance and favorable action accordingly is earnestly solicited. Should there still remain any outstanding issues, a phone call is urged from the Examiner to discuss the same.

A clean copy of the claims is provided herewith.

Respectfully submitted,

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Clean copy of the claims.

7. Immunocoprocytes isolated from exfoliated colonocytes obtained from fecal matter with a yield of about 8-10 million living colonocytes per gram of fecal matter, said immunocoprocytes being cells that express immunoglobulins selected from the group consisting of IgA, IgC, CFc, and a combination thereof.

8. The immunocoprocytes of claim 7 expressing IgA and CFc.

9. The immunocoprocytes of claim 7 expressing CFc.

26. The immunocoprocytes of claim 7 expressing a chimeric immunoglobulin Igc.